



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,214	03/01/2005	Tsuyoshi Mackawa	10525.0004	7396
22852	7590	03/17/2009		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER	
			JAISLE, CECILIA M	
			ART UNIT	PAPER NUMBER
			1624	
MAIL DATE	DELIVERY MODE			
03/17/2009	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,214	Applicant(s) MAEKAWA ET AL.
	Examiner Cecilia M. Jaisle	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,5-7,9-15,17-21,23 and 31 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 17 is/are allowed.
 6) Claim(s) 1-3,5-7,9-15,18-21,23 and 31 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED OFFICE ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on Jan. 21, 2009 after the final rejection of Sep. 17, 2008. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action of Sep. 17, 2008 has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Jan. 21, 2009 has been entered.

Rejections Under 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7, 9-15, 18-21, 23 and 31 are rejected under 35 U.S.C. 112, first paragraph, while enabling a method of making compounds of Examples 1-379, does not reasonably enable a method of making and using all compounds encompassed by claims 1-3, 5-7, 9-15, 18-21, 23 and 31. The production methods (pages 73-100, *inter alia*) fail to teach commercial availability or how to make all starting materials and intermediates required to prepare all compounds encompassed by the claims. For example, the specification fails to teach the commercial availability of or how to make all necessary starting compounds (II), (III), (I-2), (I-4), (I-5), (V), (VI), (VIII), (IX), (X), (XI), (XIII),

(XIV), (XV), (XVI) and (XIX) required to prepare all compounds encompassed by the claims. Each of the described reaction schemes can prepare only certain of the compounds encompassed by Formula I of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make, and thus to use, the invention commensurate in scope with these claims.

Because neither the prior art, nor the present specification nor both of them together teach how to prepare all compounds encompassed by the claims, it follows as a necessary corollary that the method of using all of these compounds is undisclosed. Unless Applicants can provide reference to all of the necessary starting materials and procedures required to make all of the compounds encompassed by claims 1-3, 5-7, 9-15, 18-21, 23 and 31, these claims must be limited to the supporting disclosure.

Applicants' attention is drawn to the Revised Interim Utility and Written Description Guidelines, 66 FR 1092-1099 (2001), emphasizing that "a claimed invention must have a specific and substantial utility." MPEP 2163, *et. seq.* This application's disclosure is insufficient to enable making certain of the compounds of claims based solely on disclosure of the compounds of Examples 1-379, absent disclosure of a valid method of preparing all of the claimed compounds as noted in the paragraph above. The state of the art indicates the requirement for undue experimentation.

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue." MPEP 2164.01(a). These factors include: (1) the claim breadth; (2) the nature of the invention; (3) the state of the prior

art; (4) the level of predictability in the art; (5) the amount of direction provided by the inventor; (6) the presence of working examples; and (7) the quantity of experimentation needed to make the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (Fed. Cir. 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement:

(1) Breadth of claims.

(a) Scope of the compounds. The claims cover potentially thousands of substituted pyrazole compounds in which many of the substituents are undefined.

(b) Scope of the methods of preparing the compounds. The scope of the methods is stated above and below in Point (3) Direction or Guidance. The specification contains insufficient disclosure of the preparation of all claimed compounds. The method scope is discussed above, and the specification does not disclose preparation of all claimed compounds, particularly failing to show the source of the necessary starting materials and intermediates, or the methods of preparation of the required starting materials and intermediates.

In *In re Albrecht, et al.*, 185 USPQ 590, 594 (CCPA 1975), the claimed compounds were rejected for lack of enablement, because the specification failed to show all necessary starting materials required to prepare all claimed compounds. Appellant attempted to rely on a prior US patent (Anderson) to show such starting

materials. J. Baldwin confirmed that, when appellant's claims are rejected as non-enabling for failure to show all starting materials needed to prepare their claimed compounds, appellant must show specifically all such starting materials:

However, we fail to find all of the missing [starting materials] ... necessary to prepare appellants' claimed compounds. ... It is incumbent upon appellants to show where in the Anderson *disclosure* one of ordinary skill in the art would glean the necessary information required to satisfy the enablement requirement of the first paragraph of 35 USC 112. The Anderson patent specification contains thirty examples and nine columns of text. Appellants have not pointed out precisely where enablement lies in that disclosure. It is incumbent upon appellants to rebut the assertion that their specification is not enabling.

In re Wands, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) similarly noted the requirement of the availability of biological organisms when they were necessary starting materials to support enablement of the claims:

A deposit has been held necessary for enablement where the starting materials ... are not readily available to the public. Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the ... invention from the starting materials. ... No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.

(2) The nature of the invention and predictability in the art: "[T]he scope of enablement varies inversely with the degree of unpredictability of the factors involved" and the ability to make all claimed compounds is considered to be unpredictable because all necessary starting materials and intermediates have not been shown to be available. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). In the instant case, the disclosure does not sufficiently address preparation of all claimed compounds.

(3) Direction or Guidance: The specification teaches (pages 73-100, *inter alia*) methods to make certain compounds of claims 1-3, 5-7, 9-15, 18-21, 23 and 31, but does not teach methods and required starting materials and intermediates necessary to prepare all claimed compounds. Neither the prior art, nor the present specification nor both of them together teach how to prepare all claimed compounds, especially considering the number of position isomers, homologs and further unidentified substituents encompassed thereby.

(4) State of the Prior Art: Formation of compounds is highly species-specific in organic chemistry. Note that the present claims include compounds having undefined substituents. *Albrecht* and *Wands*, discussed above, stand as evidence of the prior art acknowledgement that unless starting materials to prepare all compounds within the scope of the claims are available, the claims are not enabled. Applicants must show all necessary starting materials or limit the claims accordingly.

(5) Working Examples: The working examples have been fully discussed in Point 3) Direction or Guidance, above. Pharmacological activity in general is unpredictable. In applications involving physiological activity, such as the present,

The first paragraph of 35 U.S.C. 112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

Plant Genetic Syst. v. DeKalb Genet., 65 USPQ2d 1452, 1456 (Fed. Cir. 2003).

"[T]he scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

(6) Skill of those in the art: The state of the art supports that to successfully prepare all compounds within the scope of the claims requires specific individualized disclosure, particularly considering that many of the intended substituents are undefined.

(7) The quantity of experimentation needed: Based on the disclosure content, one skilled in the pharmaceutical arts would have an undue burden to make and use the invention, since the disclosure gives the skilled artisan inadequate guidance regarding making all claimed compounds, as stated above.

Discussion of the above factors demonstrates that the present application insufficiently enables the present claims. In view of claim breath, unpredictability of methods of making the claimed compounds, lack of definition of all compound substituents, one of ordinary skill in this art would undergo an undue amount of experimentation to make the instantly claimed invention commensurate with the claim scope.

MPEP 2164.01(a) states,

A conclusion of lack of enablement means that, based on the evidence regarding each of the above [Wand] factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

This is a circumstance where the "specification is evidence of its own inadequacy." *In re Rainer*, 153 USPQ 802, 807. All the claimed compounds cannot be simply willed into existence. *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 states:

The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist ... the

examples of the '881 patent do not produce the postulated compounds ...
[T]here is ... no evidence that such compounds even exist.

The same circumstance appears true here. Applicants must show making and using all claimed compounds or limit the claims accordingly.

Claims 20, 21, 23-27 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating a mammal with type 2 diabetes (claim 20), hyperlipidemia (claim 21) and/or impaired glucose tolerance (claim 23). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not provide competent evidence that the instantly disclosed tests are predictive of all uses disclosed and embraced by the claims. Substantiation of utility and its scope is required when utility is "speculative," "sufficiently unusual" or not provided. See *Ex parte Jovanovics, et al.*, 211 USPQ 907, 909 (BPAI 1981). Also, note *Hoffman v. Klaus*, 9 USPQ2d 1657 (BPAI 1988) and *Ex parte Powers*, 220 USPQ 924 (BPAI 1982) regarding types of testing needed to support *in vivo* uses.

Applicants' attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 66 FR 1092-1099 (2001), emphasizing that "a claimed invention must have a specific and substantial utility." See also MPEP 2163, *et. seq.* This application's disclosure is insufficient to enable the instantly claimed methods. The state of the art indicates the requirement for undue experimentation.

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue.” MPEP 2164.01(a). These factors include: (1) the claim breadth; (2) the nature of the invention; (3) the state of the prior art; (4) the level of predictability in the art; (5) the amount of direction provided by the inventor; (6) the presence of working examples; and (7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(reversing the PTO’s determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (Fed. Cir. 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement:

(1) Breadth of claims.

(a) Scope of the methods. The method claims cover the use of substituted pyrazole compounds and pharmaceutically acceptable salts.

(b) Scope of the disorders covered. The scope of the disorders said to be treated by the claimed methods are highlighted above and further discussed in the previous Office Action.

(2) The nature of the invention and predictability in the art: Therapeutic use of substituted pyrazoles and salts in preventing and treating disorders recited above. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally consid-

ered to be an unpredictable factor. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

(3) Direction or Guidance: That provided is very limited. Dosage range information is meager; it would require extensive experimentation to determine specific dosage for a specific recited disorder, mode of administration and therapeutic regimen. The dosage is generic; the same for many disorders the specification covers. No specific direction or guidance gives a regimen or dosage effective specifically for various types of diseases. No dosage or therapeutic regimen is present to direct the skilled artisan to protect a potential host from all named disorders.

(4) State of the Prior Art: Kebede, et al., Diabetes 57:2432-2437, 2008 reports research that raises "doubts on the validity of a therapeutic approach based on GPR40 antagonism for the treatment of type 2 diabetes.

Calkin, et al., Nephrol. Dial. Transplant. (2006), 21:2399-2405, points to the need for further research:

In summary, the PPAR-alpha agonist, gemfibrozil, the PPAR-gamma, rosiglitazone and the PPAR-alpha/gamma co-agonist, compound 3q, have equivalent renoprotective actions in experimental diabetes, over and above effects on plasma, glucose, blood pressure or lipid levels. This finding is consistent with the important role of the PPAR signaling system in diabetic complications. Moreover, these benefits correlate with the direct anti-atherogenic effects of PPAR agonists observed in the diabetic vasculature. The clinical relevance of this finding remains to be established, given the negative effects of the dual agonist, muraglitazar in patients with diabetes and equivocal outcomes with side effects observed in the recent FIELD and proACTIVE studies.

Wieser, et al., PPAR Res. 2008; 2008: 527048, reports alarming findings:

Ongoing basic studies have elucidated the metabolic, antiinflammatory, and angiogenic benefits of PPAR $\alpha/\beta/\delta$ and PPAR $\gamma/\beta/\delta$ dual agonists and PPAR pan agonists for treatment purposes. However, some experimental and clinical data have uncovered unfortunate side effects of PPAR

ligands, including cancer progression and increased cardiac event rates. New generations of PPAR modulators are under development and these promise to be more receptor-specific, and hopefully will activate only a specific subset of target genes and metabolic pathways to reduce untoward side effects. The potential role of PPARs in regulation of inflammation and angiogenesis is intriguing and warrants further studies. We submit that PPAR agonists may become beneficial drugs for pregnancy-specific diseases, once their risks have been fully evaluated.

Ability of claimed methods to treat all disorders asserted above remains open to proof. A skilled person in this art would need undue experimentation.

(5) Working Examples: The disclosure fails to correlate the test results in the specification to the treatments construed by the claims. The specification merely prophesies that the methods will treat prevent all disorders mentioned above.

The specification states that the methods treat all claimed disorders, for which Applicants provide insufficient evidence. Applicants have not provided competent evidence of known tests highly predictive for all disorders embraced by the claim language for the intended host. Pharmacological activity in general is unpredictable. In applications involving physiological activity, such as the present,

"The first paragraph of 35 U.S.C. 112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."

Plant Genetic Syst. v. DeKalb Genetics, 65 USPQ2d 1452, 1456 (Fed. Cir. 2003). "[T]he scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 166 USPQ 18 (CCPA 1970).

(6) Skill of those in the art: See the discussion above of Kebede, Calkin and Wieser. The state of the art supports that successful treatment and prevention of all disorders recited is a subject for further investigation.

(7) The quantity of experimentation needed: Based on the disclosure content, to use the invention would place an undue burden on one skilled in the pharmaceutical arts, since the disclosure gives the skilled artisan inadequate guidance regarding pharmaceutical use, for the reasons stated above.

The discussion of the above factors demonstrates that the present application sufficiently lacks enablement of the present claims. In view of the breath of the claims, the pharmaceutical nature of the invention, the unpredictability of relationship between 5-HT2 receptor antagonist activity and treatment and prevention of all disorders, one of ordinary skill in this art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states,

A conclusion of lack of enablement means that, based on the evidence regarding each of the above [Wand] factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Response to Remarks of 01/21/2009

Applicants reference *In re Anthony*, 162 USPQ 594, supposedly in support of their position that this disclosure sufficiently teaches how to use the present claims. However, *Anthony* was a case regarding the sufficiency of the teaching

of utility under 35 USC 101. The present rejection is based on 35 USC 112, paragraph 1, and *Anthony* has no relevance to this situation.

Applicants assert Kebede is not relevant as the claim based on GPR4-antagonism has been canceled. However, GPR4-antagonism by the present compounds is one basis for Applicants' hypothesis that the present compounds will treat type-2 diabetes, a hypothesis that Kebede does not support.

Wieser confirms that experimental and clinical data uncovered PPAR ligand side effects, including progression of cancer, increased cardiac event rates, and requires further evaluation before they can become potential drugs.

Calkin reports that the clinical relevance of their findings must still be established, particularly in light of the negative effects of the dual agonist, muraglitazar, in diabetic patients and equivocal outcomes with side effects observed in the recent FIELD and proACTIVE studies.

Regarding muraglitazar, a Bristol-Myers Squibb PPAR agonist, its further development has been discontinued as of May 2006. Data on muraglitazar is relatively less due to recent introduction of this agent. One double-blind randomized clinical trial comparing muraglitazar and pioglitazone found that effects of the former were favorable in terms of HDL-C increase, decrease in total cholesterol, apolipoprotein B, triglycerides and a greater reduction in HbA1c ($P<0.0001$ for all comparisons). However, the muraglitazar group had a higher all-cause mortality, greater incidence of edema and heart failure and more weight gain compared to the pioglitazone group. A meta-analysis of the phase 2 and 3 clinical trials of

muraglitazar revealed that it was associated with a greater incidence of myocardial infarction, stroke, transient ischemic attacks and congestive heart failure when compared to placebo or pioglitazone. Wikipedia, Muraglitazar, updated Dec. 26, 2008, <<http://en.wikipedia.org/wiki/Muraglitazar>>, downloaded 3/8/2009.

The teachings of Iwatsuka, Kimura, Alberts, and Depres have been carefully considered, but they are not seen to overcome the more recent and relevant teachings of Kebede, Calkin and Wieser, and the discussion of muraglitazar, all considered in detail above.

Note also that Anantaranayan, cited and discussed below, describes a compound that falls within the genus of the claimed compounds and methods, but is not described as evidencing efficacy for treating a mammal with type 2 diabetes, hyperlipidemia or impaired glucose tolerance. This further calls into question whether all of the claimed compounds evidence such properties, especially considering claimed compounds with unidentified substituents.

The record fails to establish that the skilled practitioner would be able to use the present methods as broadly as claimed without having to undergo extensive inventive research.

Sitrick v. Dreamworks LLC, 85 USPQ2d 1826, 1830 (Fed. Cir. 2008) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable all of the embodiments. "Because the asserted claims are broad enough to cover both [embodiments], the [specification] must enable both embodiments." Here, the claims at issue cover many methods and do not enable all of them.

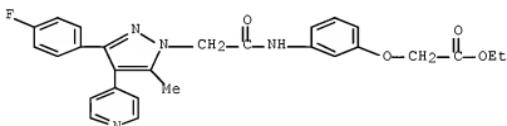
Automotive Tech. Int'l. v. BMW of N. America, Inc., 84 USPQ2d 1108, 1116 (Fed. Cir. 2007) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable one of the embodiments. "Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both [embodiments], which the specification fails to do." Here, the claims at issue cover many methods and do not enable all of them.

Rejections Under 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 7, 9, 11, 12, 14, 18 and 19 are rejected under 35 USC 102(a) over US 6514977, Anantanarayan, et al., entitled to the date of 19970522, describing RN 216528-98-2 Acetic acid, 2-[3-[[2-[3-(4-fluorophenyl)-5-methyl-4-(4-pyridinyl)-1H-pyrazol-1-yl]acetyl]amino]phenoxy]-, ethyl ester,



, useful to treat

inflammation, arthritis, asthma and other disorders mediated by p38 kinase and TNF α .

Allowed Claim

Claim 17 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624